DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

M130Mn

October 4, 1999

xc: HFI-35
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 00 - 01

Jeffrey M. Reed
President
Reed's Market and Salad Center
4737 W. Center Street
Milwaukee, Wisconsin 53210

Dear Mr. Reed:

The Food and Drug Administration (FDA) conducted an inspection at your salad and seafood salad operations at the above facility on July 1-2, and 6, 1999, to determine your compliance with the Seafood HACCP and Good Manufacturing Practice (GMP) regulations denoted in Title 21, Code of Federal Regulations, Parts 123 and 110 (21 CFR 123 and 110), respectively. At the conclusion of this inspection the investigator issued a list of inspectional observations on form FDA-483 and discussed them with you. The form FDA-483 listed:

Failure to monitor and record sanitation procedures and conditions to ensure the safety of your ready-to-eat seafood products, shrimp, tuna and crab (surimi) salads. Conditions observed included:

1. Employee's arms touched food in lugs and employee touched door handles without removing or changing gloves used to prepare foods.

2. Equipment and surfaces that come in contact with food were inadequately cleaned or sanitized. Employees could not demonstrate how to prepare sanitizing solution.

3. Food residue build-up was noted on food racks and pails.

4. Condensate was dripping from the ceiling in the walk-in food coolers.

5. Evidence of rodents was found in equipment storage rooms and flies in the processing room.

Please refer to the form FDA-483 dated July 6, 1999, for a more detailed listing of the objectionable findings of this inspection. Note that these are repeat violations that you promised to correct at the July 17, 1998, inspection. Also note that our Minneapolis District laboratory confirmed the presence of rat droppings in your facility from Collection Report 33671.

The listing of these inspectional observations is not intended to be an all-inclusive list of the violations at your facility. As the most responsible individual at your facility, you are responsible for ensuring your operation is in compliance with both local and federal requirements. These findings cause the seafood products manufactured at your facility to be adulterated according to Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act) in that they were manufactured and held under conditions whereby they may have been rendered injurious to health. The adulteration of a previously unadulterated food after shipment in interstate commerce and held for sale is prohibited by Section 301 of the Act.

Within 15 working days of receipt of this letter please provide a written response detailing the actions you have taken to correct these violations and prevent their recurrence. Also include a timeline as to the projected completion dates for these corrective actions so we may re-inspect to verify the effectiveness of your corrective action plan.

If you fail to take timely corrective actions, FDA may initiate legal actions against you and/or your products in the form of injunction and/or product seizure.

Your response and any questions you may have regarding this matter may be directed to Compliance Officer Thomas P. Nelson at the address indicated on the letterhead or (612) 334-4100 ext. 177.

Sincerely,

Edwin S. Dee
Acting Director
Minneapolis District

TPN/ccl